

Got “Hormone-Free” Milk?: Your State May Have Enough Interest to Let You Know

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INTRODUCTION

The food we consume and the milk we drink are affected by our world’s search for new technology to produce more at a lower cost. Food manufacturers and drug companies have undertaken the controversial practice of genetically engineering food and artificially imitating natural processes of animals in order to produce a bigger tomato, allow corn to naturally ward off pests, and increase a cow’s lactation. Sometimes, however, technology thrusts us into the world of the unknown and advancements may come at a price uncalculated or unnoticed by all—especially when toying with Mother Nature herself. Although there is much to be said about genetically engineered foods and the technology used, the focus of this Note is on the use of Recombinant Bovine Somatotropin Hormone (“rBST”), a hormone injected into cows to increase milk production.

The somatotropin hormone exists naturally in the pituitary glands of a cow and controls the cow’s ability to lactate.¹ Monsanto, a large American drug company, created a synthetic form of this hormone and, after the U.S. Food and Drug Administration’s (“FDA”) approval of its use in 1993,² began distributing the drug to the dairy industry in America under the name Posilac.³ Posilac is estimated to increase a cow’s production of milk between seventeen⁴ and forty percent⁵ per day. Some criticize the use of the hormone for its possible link to increased pus production, shorter life-span, and diseases like mastitis⁶ in cows.⁷ There is also controversy surrounding the studies conducted on the effects consumption of milk from a cow treated with rBST has on human health.

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1. Kristine Cerro, Comment, *High-Tech Cows: The BST Controversy*, 6 SAN JOAQUIN AGRIC. L. REV. 163, 164-65 (1996) (citing *BST Fact Sheet*, NEWSCAST, Summer 1993, at 4).

2. *Id.* at 163.

3. Terence J. Centner & Kyle W. Lathrop, *Labeling rBST-Derived Milk Products: State Responses to Federal Law*, 45 U. KAN. L. REV. 511, 515 (1997).

4. See Bruce W. Marion & Robert L. Wills, *A Prospective Assessment of the Impacts of Bovine Somatotropin: A Case Study of Wisconsin*, 72 AM. J. AGRIC. ECON. 326, 327 (1990).

5. David Aboulafia, *Pushing RBST: How the Law and the Political Process Were Used to Sell Recombinant Bovine Somatotropin to America*, 15 PACE ENVTL. L. REV. 603, 605 (1998).

6. Mastitis is “an inflammation of the udder and is generally accepted as the most costly and widespread disease of the dairy industry.” Cerro, *supra* note 1, at 178 n.117.

7. See *Ben & Jerry’s Thoughts About Bovine Growth Hormone (BGH)*, at <http://www.benjerry.com/bgh/index.html> (last visited Apr. 3, 2001) (citing studies that report a seventy-nine percent increase in mastitis, reduced pregnancy rates, cystic ovaries, lacerations, digestive disorders, and calluses of the knee) [hereinafter *Ben & Jerry’s*].

Not long after the FDA approved the use of rBST, companies and farmers employed various labels on their dairy products indicating that their products did not come from treated cows—instigating court battles between those manufacturers using rBST and the dairy farmers using no hormones. In reaction to the confusion, the FDA issued an interim opinion outlining the permissibility of farmers and grocery stores labeling their dairy products and providing guidance on how to label legally and appropriately.⁸ The guidelines provided that labeling occur on a voluntary basis and that all labels contain the following statement: “[N]o significant difference has been shown between milk derived from rBST-treated and non-rBST-treated cows.”⁹ The FDA did not make any of the labeling mandatory and was not clear initially on whether they permitted mandatory labeling laws—leaving it up to the states to adopt their own laws. Some states refused to allow labeling of any kind,¹⁰ others adopted the voluntary labeling provided by the FDA’s interim, and a few states attempted to issue mandatory labeling laws.¹¹ The one state to enact a mandatory labeling law, Vermont, found itself in a court battle with dairy producers who were arguing an infringement on their First Amendment rights to speak and not to speak.¹² While the court ruled against Vermont, the two-judge majority left an evidentiary door open—stating that with more evidence to support citizens’ concern, Vermont may be able to establish successfully a substantial state interest and enact a mandatory labeling law.¹³

Part I of this Note will discuss the court case that struck down the mandatory labeling law in Vermont and set forth the court’s reasoning. Part II will assist Vermont and other states wishing to pass mandatory labeling laws in walking through the door left open by the court by providing new and compelling evidence that has surfaced since the case was decided in 1996. This evidence includes new research regarding the reactions of citizens to rBST, regulations of rBST in other nations, new concern over human health issues, allegations and accusations regarding the objectivity of the FDA, and evidence of bullying tactics by Monsanto. Part III will discuss the current stance other states are taking with regard to mandatory labeling. Finally, this Note will conclude with suggestions regarding how Vermont and other

8. Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows That Have Not Been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279 (Feb. 10, 1994).

9. *Biotechnology: Interim Voluntary Guidance on BST Issued by FDA for Milk Producers*, 17 Chemical Reg. Rep. (BNA) 1916 (Feb. 11, 1994), WL 17 CHEM 1916.

10. Illinois was one such state until Ben & Jerry’s, Inc. filed a lawsuit stating that their constitutional rights were being infringed upon by Illinois’s law making the label “rBGH-free” illegal to place on their products. *Ben & Jerry’s Homemade, Inc. v. Lumpkin*, No. 96-C2748, 1996 U.S. Dist. LEXIS 12469, at *2 (N.D. Ill. Aug. 27, 1996). The case settled with Illinois allowing the voluntary labeling of food products and a compromise as to the language used on the labels. *Ben & Jerry’s, State in Accord on Growth Hormone Statement*, CHI. TRIB., Aug. 14, 1997, at 4.

11. See VT. STAT. ANN. tit. 6, § 2754(c) (repealed 1998); Aboulafia, *supra* note 5, at 621-22 (stating that attorney generals from New York, Wisconsin, and Texas all campaigned for mandatory labeling laws).

12. See *Int’l Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67 (2d Cir. 1996).

13. See *id.* at 74.

states can be successful in defending such laws in court and why their success matters for consumers.

I. *INTERNATIONAL DAIRY FOODS ASS'N V. AMESTOY*¹⁴

In response to the overwhelming concern of its citizens following the approval and use of rBST, the Vermont state legislature passed a statute *requiring* the labeling of food that contains or possibly contains dairy product from a cow injected with the hormone.¹⁵ The regulations promulgated pursuant to that statute required manufacturers to place a blue dot on their products if any part was from a treated cow and required retailers to post a sign explaining that products with a blue dot "contain or may contain milk from rBST-treated cows."¹⁶ In compliance with FDA guidelines, Vermont regulations required the signs to state that "the [FDA] has determined that there is no significant difference between milk from treated and untreated cows."¹⁷ The regulations also stated that the sign must include that the labeling was required by the State of Vermont in order to help "consumers make informed shopping decisions."¹⁸

The International Dairy Foods Association ("IDFA") immediately retaliated by taking the State of Vermont to court, arguing that the statute was unconstitutional.¹⁹ Vermont asserted that strong consumer concern regarding the effects of rBST on cows and humans and the ability of its citizens to make informed choices about the dairy products they buy led it to issue the mandatory labeling law. Vermont argued that requiring labels on dairy products was the most appropriate method for appeasing consumer concerns and placing the decision about whether to consume milk from cows treated with rBST where it belongs—in the hands of the consumers. The district court denied IDFA summary judgment, concluding that the State of Vermont had a substantial interest in the concerns of its citizens regarding the use of rBST.²⁰ The appellate court reversed asserting that citizen concern and desire for labeling in order to make choices as consumers (the two interests advanced by Vermont) were not sufficient enough reasons for impeding on the commercial speech right "not to speak" guaranteed by the Constitution.²¹

The appellate court followed the four prong test set out in *Central Hudson Gas & Electric Corp. v. Public Service Commissioner*²² in order to evaluate the

14. 92 F.3d 67 (2d Cir. 1996).

15. VT. STAT. ANN. tit. 6, § 2754(c).

16. *Amestoy*, 92 F.3d at 70 (emphasis omitted) (quoting Adopted Rules: rBST Notification and Labeling Regulations Relating to Milk and Milk Products, Vt. Gov't Reg. § 3.1b (1995)).

17. *Id.* (quoting Adopted Rules: rBST Notification and Labeling Regulations Relating to Milk and Milk Products, Vt. Gov't Reg. § 3.1b (1995)).

18. *Id.* (quoting Adopted Rules: rBST Notification and Labeling Regulations Relating to Milk and Milk Products, Vt. Gov't Reg. § 3.1b (1995)).

19. *Id.*

20. *Int'l Dairy Foods Ass'n v. Amestoy*, 898 F. Supp. 246, 254 (D. Vt. 1995), *rev'd*, 92 F.3d 67 (2d Cir. 1996).

21. *Amestoy*, 92 F.3d at 71.

22. 447 U.S. 557 (1980).

constitutionality of the statute in question.²³ The four parts are (1) whether the speech is commercial, (2) whether the government's interest is substantial, (3) whether the labeling law directly serves the interest asserted by the government, and (4) whether the labeling law is no more restrictive than necessary.²⁴ The appellate court concluded that, even though the speech was commercial in nature (a type of speech afforded less protection under the First Amendment), Vermont had not satisfied the second prong of the test—whether the government's interest is *substantial*.²⁵ The court engaged in a balancing test in order to determine whether the second prong had been satisfied.²⁶ The judges weighed the possible harmful effect labeling would have on the sale of dairy products from treated cows against the interest Vermont citizens have in making conscious choices about the products they buy.²⁷ Despite the fact that the district court found enough evidence to support the consumer concern argument,²⁸ the appellate court reversed in a 2-1 decision, dismissing the concern as mere unsubstantiated "curiosity."²⁹

Judge Leval raised strong objections in his dissenting opinion that deserve attention. He argued that the interests considered by the court in their balancing test were a watered down version of the arguments Vermont advanced.³⁰ The majority determined that Vermont was requiring labeling *solely* because of consumer curiosity.³¹ The majority failed, in Leval's opinion, to recognize all of the legitimate reasons surrounding consumer concern and the desire to have labels in order to make more informed choices. He offered examples of legitimate reasons for consumer concern such as ethical and moral concerns regarding the health and well-being of cows, effects on human health, skepticism surrounding the thoroughness and validity of the FDA's approval, and the impact the use of rBST would have on small dairy farmers.³²

Judge Leval also criticized the majority's use of the First Amendment to strike down a state law mandating disclosure of information consumers reasonably want when purchasing food items, stating that the outcome "stands the Amendment on its ear."³³ The First Amendment searches for truthful speech and the labels that Vermont sought to mandate contained truthful and accurate information.³⁴ Leval asserted that the plaintiff's concern that it be forced to say something they did not believe, which is unconstitutional under *Wooley v. Maynard*,³⁵ is unfounded considering the precise

23. *Id.* at 562-63.

24. *Id.* at 566.

25. *Amestoy*, 92 F.3d at 73.

26. *Id.* at 72-74.

27. *Id.*

28. *See Int'l Dairy Foods Ass'n v. Amestoy*, 898 F. Supp. 246, 254 (D. Vt. 1995), *rev'd*, 92 F.3d 67 (2d Cir. 1996).

29. *Amestoy*, 92 F.3d at 73 n.1.

30. *See id.* at 76 (Leval, J., dissenting).

31. *Id.* at 73 n.1.

32. *Id.* at 75-76 (Leval, J., dissenting). For purposes of this Note, the impact rBST use would have on small dairy farmers will not be discussed in any kind of detail.

33. *Id.* at 74.

34. *See id.*

35. 430 U.S. 705, 714 (1977).

language of the sign which recognized the FDA's findings of no harm.³⁶ The sign also attributed the labeling to Vermont's law in order to not mislead consumers into thinking the manufacturers voluntarily labeled.³⁷

The majority stated that the public's desire to know has never been found to be a legitimate state interest with regard to speech.³⁸ Leval, after criticizing the majority's failure to regard the district court's report containing all of the reasons and evidence advanced by Vermont, pointed to several court cases in which this issue was considered.³⁹ In *Liquormart, Inc. v. Rhode Island*,⁴⁰ the Supreme Court established that, when concerning commercial speech, the interest protected by the First Amendment is the "public's interest in receiving accurate commercial information."⁴¹ In that case, the Court struck down a state law that made liquor dealers' advertising of prices illegal. The Court determined that when a state mandated the disclosure of "beneficial consumer information, the purpose of its regulation is consistent with the reasons for according constitutional protection to commercial speech."⁴² In his concurring opinion, Justice Thomas stressed that an attempt to keep lawful consumers ignorant in order to "manipulate their choices in the marketplace" is "per se illegitimate."⁴³

Leval asserted that the majority erred in not considering Vermont's interest in its consumer concern substantial.⁴⁴ He argued that the evidence and arguments produced by Vermont were even stronger than those present in some cases in which the Supreme Court found a substantial interest.⁴⁵ He criticized the court's decision as "depriv[ing] Vermont of the right to protect its consumers by requiring truthful disclosure on a subject of legitimate public concern."⁴⁶

Although the majority found that Vermont did not provide enough evidence to support its reasoning regarding public concern, Leval was comforted by the fact that the door has been left open for Vermont to do just that—provide enough evidence to win.⁴⁷ He also established that the court's findings have no bearing on any case in which the state provides an interest in addition to the "gratification of consumer curiosity."⁴⁸

As Judge Leval noted in his dissenting opinion, Vermonters and other consumers

36. *Amestoy*, 92 F.3d at 79-80 (Leval, J., dissenting).

37. *See id.*

38. *Id.* at 73.

39. *See id.* at 80-81 (Leval, J., dissenting).

40. 517 U.S. 484 (1996).

41. *Id.* at 496.

42. *Id.* at 501.

43. *Id.* at 518 (Thomas, J., concurring).

44. *Amestoy*, 92 F.3d at 76 (Leval, J., dissenting).

45. *Id.* at 78 (comparing *Florida Bar v. Went For It, Inc.*, 515 U.S. 618 (1995) (deeming the state's interest in privacy and tranquility sufficient to uphold a thirty-day waiting period by lawyers before solicitation of business from accident victims), with *City of Cincinnati v. Discovery Network*, 507 U.S. 410 (1993) (establishing safety and aesthetics as substantial state interests regarding a law regulating commercial handbill distribution on public property)).

46. *Id.* at 81.

47. *See id.*

48. *Id.*

across the nation *have* a legitimate concern—Vermont and other states simply need to advance these reasons thoroughly in court. As noted earlier, he offered four reasons why consumers may wish to know whether the dairy products they eat come from a treated cow.⁴⁹ Judge Leval pointed out that with enough evidence, any one of the four on its own can stand as a substantial interest.⁵⁰

II. RECENT FINDINGS SINCE *AMESTOY*

The court in *Amestoy* decided in favor of the dairy industry on the grounds that Vermont had not supplied enough evidence to substantiate its interest in consumer concern.⁵¹ The court also stated that the evidence that Vermont could have presented regarding the use of rBST would not have been enough considering the “exhaustive studies” the FDA had conducted.⁵² The court, therefore, placed considerable faith in the FDA findings and had doubts that Vermont could have refuted them to the degree necessary to render a judgment in its favor. The district court and dissenting judge in the appellate court concluded that enough evidence existed when the case was argued before them. This Note proposes that even though Vermont may have provided enough compelling evidence in 1995, significantly more research, studies, consumer reactions, and reasons to doubt the FDA have developed since the holding.

A. Outside the United States

Perhaps the biggest additions to the debate of rBST since the Second Circuit decided *Amestoy* are the recent decisions by Canada and the European Union to ban the use of rBST.⁵³ In August of 1994, the Canadian government postponed the sale and use of rBST until July of 1995 to allow for sufficiently substantial testing in order to ensure a well-informed public.⁵⁴ Health Canada (the FDA’s Canadian counterpart) continued to delay its approval and, in December of 1998, again declined to permit the sale and use of the hormone, citing the need for more studies.⁵⁵ In 1998, a “leaked” report by scientists studying rBST for Health Canada revealed “numerous gaps” in the FDA’s data on human and animal safety.⁵⁶

Health Canada is also concerned about the actions of their own regulatory agency and the coercive behavior of Monsanto.⁵⁷ Five Health Canada scientists testified

49. See *supra* text accompanying note 32.

50. *Amestoy*, 92 F.3d at 78 (Leval, J., dissenting).

51. See *id.* at 74.

52. *Id.* at 73.

53. Denmark, Sweden, Norway, the Netherlands, Australia, New Zealand, and Argentina have also banned the sale and use of rBST. Aboulafia, *supra* note 5, at 621.

54. See *Canada Delays Introduction of BST: Bovine Somatotropin*, AGRICULTURE, Aug. 19, 1994, at N3, 1994 WL 13042597.

55. See Emily Green, *The Spud America Didn't Like*, NEW STATESMAN, Feb. 26, 1999, at 18, 18; see also Melinda Fulmer, *Organic Milk Pours into Mainstream*, L.A. TIMES, July 24, 1999, at C1.

56. Kelly Morris, *Bovine Somatotropin—Who's Crying over Spilt Milk?*, 353 LANCET 306, 306 (1999).

57. See Laura Eggertson, *Experts Raise Concerns over Cow Hormone*, TORONTO STAR,

about their fears to the Senate Agriculture Committee and accused Monsanto of bullying tactics.⁵⁸ "We have been pressured and coerced to pass drugs of questionable safety, including rBST. That is our concern," stated Shiv Chopra, a veterinarian and reviewer in Health Canada's Bureau of Veterinary Drugs.⁵⁹ The scientists noted that the files on rBST were under lock and key—accessible only through one official.⁶⁰

The Canadian press has reported allegations regarding stolen files and a bribe by Monsanto to the government for millions of dollars in exchange for approval of their drug without further submissions to clinical trials, although these allegations have not been entirely substantiated.⁶¹ These findings and questionable tactics continue to convince the Canadian government that not enough is known about the effects of using rBST in order to declare the drug safe. In January 1999, Canada officially banned the use of rBST.⁶²

Similarly, the European Union requested a moratorium in 1989 to research further the effects that injecting rBST in dairy cows has on human and cow health.⁶³ United Kingdom officials declared animal welfare of "vital importance" to their farmers.⁶⁴ Contrary to initial statements by the FDA that rBST does not impact the incidence or duration of mastitis in cows,⁶⁵ studies conducted by European scientists indicate that injecting cows with rBST increased the incidence of not only mastitis, but also foot disease, reproductive disorders, and overall avoidable distress as well.⁶⁶ On December 17, 1999, European Union Ministers approved the European Commission's permanent ban on the use of rBST and the sale of dairy products containing milk from treated cows.⁶⁷

Not only has the concern in other nations heightened fear in American consumers,

Oct. 23, 1998, at A11, LEXIS, News Library, TSTAR File.

58. *See id.*

59. *Id.*

60. *Id.*

61. *Id.*

62. *Health Canada Rejects Bovine Growth Hormone in Canada*, CANADIAN CORP. NEWSWIRE, Jan. 14, 1999, LEXIS, News Library, CCN File (noting that, even though the Human Health Committee has yet to uncover significant human health concerns, the risks to the health of the animals is enough to ban the use altogether).

63. Cerro, *supra* note 1, at 183 n.145.

64. Peter Gruner, *Come Clean on Secret GM Milk Hormone Trials, Ministers Told*, EVENING STANDARD (London), June 23, 1999, at 25, LEXIS, News Library, ESTAND File.

65. *See* Stauber v. Shalala, 895 F. Supp. 1178, 1192-93 (W.D. Wis. 1995) (noting the initial findings of the FDA); *cf.* D.G. McClary et al., *The Effects of a Sustained-Release Recombinant Bovine Somatotropin (Somidobove) on Udder Health for a Full Lactation*, 77 J. DAIRY SCI. 2261, 2270 (1994).

66. *Consumers Mop Up in Milk War: An Amazing U-Turn Has Repelled American Hormone-Treated Milk*, GUARDIAN (London), July 22, 1999, at 20, LEXIS, News Library, GUARDN File [hereinafter *Consumers Mop Up*]. Even the label placed on Posilac by the manufacturer indicates that injections of rBST may cause a variety of serious health problems in the cows. *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 78 (2d Cir. 1996) (Leval, J., dissenting); *see also* *Ben & Jerry's*, *supra* note 7, at <http://www.benjerry.com/bgh/index.html>.

67. Likewise, since the FDA's approval of Monsanto's Posilac in 1993, no other industrialized nation has licensed Posilac. Green, *supra* note 55, at 18.

but it has called into question the reaction of the FDA to these countries' actions.⁶⁸ The FDA's mission statement specifically states that the agency will "participate through appropriate processes with representatives of other countries to . . . harmonize regulatory requirements, and achieve appropriate reciprocal arrangements."⁶⁹

Opponents of rBST criticize the FDA for not fully considering the actions taken by foreign countries and issues such as international trade when that is a duty enumerated in the FDA's mission statement.⁷⁰ These opponents contend that, if the FDA had considered these issues, the ultimate decision regarding labeling may have been different.⁷¹

B. Human Health Concerns

Despite the numerous reassurances given by FDA officials⁷² and other government officers,⁷³ there is evidence of concern among the American public.⁷⁴ When *Amestoy* was decided, the court dismissed consumer concern as mere "curiosity" and did not view that interest as "substantial."⁷⁵ The court also indicated that Vermont would have been unable to refute successfully the FDA's findings.⁷⁶ Although there is little hard evidence, given that the drug was developed, approved, and used too recently to have any compelling long-term studies, more research has surfaced justifying consumer concern and doubts and questioning the thoroughness and care with which the FDA conducted its studies.

68. See Lara Beth Winn, *Special Labeling Requirements for Genetically Engineered Food: How Sound Are the Analytical Frameworks Used by FDA and Food Producers?*, 54 FOOD & DRUG L.J. 667, 678-79 (1999).

69. *Id.* at 679 (quoting FDA, *FDA's Mission*, at www.fda.gov/opacom/morechoices/mission.html (last modified Oct. 19, 1998)).

70. *See id.*

71. *See id.*

72. "[T]he public can be confident that milk and meat from rBST-treated cows is safe to consume." Cerro, *supra* note 1, at 176 (citing Press Release, Susan M. Cruzan, FDA Approves New Animal Drug Sometribove (Nov. 5, 1993) (quoting FDA Commissioner David A. Kessler), <http://www.fda.gov/bbs/topics/NEWS/NEW00443.html>).

73. "Milk from cows given supplemental bovine somatotropin is the same as any other milk . . ." *Id.* at 176 (quoting former U.S. Surgeon General C. Everett Koop).

74. As many as three-fourths of the people are said to be concerned about genetically engineered foods. Cerro, *supra* note 1, at 169 (citing William B. Lacy et al., *Emerging Trends, Consequences, and Policy Issues in Agricultural Biotechnology*, in BOVINE SOMATOTROPIN & EMERGING ISSUES 3, 5-6 (Milton C. Hallberg ed., 1992)). Another indication of the growing concern among consumers is the increase in sales of organic products. Organic farmers in Minnesota claimed at one point that their sales have more than quadrupled since 1993 when the hormone was approved. *Id.*

75. *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 73 (2d Cir. 1996).

76. *Id.* at 74.

1. Insulin Growth Factor-One and Its Potential Effects

There is much concern that the use of rBST increases levels of Insulin Growth Factor-One ("IGF-1") in the milk. Studies conducted by the FDA concluded that IGF-1 does increase but that the effects on humans are harmless.⁷⁷ According to the Council of Scientific Affairs, a subgroup of the American Medical Association, these assurances were based upon minimal data and further research should have been conducted *before* the FDA approved the hormone's use.⁷⁸ Contradicting studies have emerged since the FDA's assertion regarding the effects of IGF-1. One study indicates that IGF-1 stimulates growth of intestinal cells—possibly leading to the risk of colon cancer.⁷⁹ Other studies link increased levels of IGF-1 consumption with increased risks of breast and gastrointestinal cancers.⁸⁰ Although more evidence is needed, the potential risks identified by various studies have some scientists demanding that they should continue extensively researching rBST in order to accurately assess these risks before the FDA approves the hormone's use.⁸¹

2. Possibilities of Antibiotic Residue

Perhaps the greatest fear of antihormone advocates focuses not on the higher incidence of pus and bacteria in the milk⁸² but on the powerful antibiotics injected in cows to treat the increase of pus, mastitis, and other diseases.⁸³ Long-term exposure to even small amounts of antibiotics can lead to the development of resistance in humans.⁸⁴ The Center for Disease Control ("CDC") recently issued numerous warnings for encephalitis and streptococcus pneumoniae bacteria that cause meningitis, pneumonia, and other diseases in which antibiotics are ineffective,⁸⁵

77. Council on Scientific Affairs, Am. Med. Ass'n, *Biotechnology and the American Agricultural Industry*, 265 JAMA 1429, 1433 (1991).

78. *Id.*

79. Michael Hansen et al., *Potential Public Health Impacts of the Use of Recombinant Bovine Somatotropin in Dairy Production*, CONSUMER UNION, ¶ 1 (Sept. 1997) (citing Susan S. Devesa et al., *Recent Cancer Trends in the United States*, 87 J. NAT'L CANCER INST. 175, 175-82 (1995) (pointing out that colon cancer is the third most common cancer mortality in the United States)), at <http://www.consumer.org/food/bgh-codex.html>.

80. John Grogan & Cheryl Long, *The Problem with Genetic Engineering*, ORGANIC GARDENING, Jan. & Feb. 2000, at 42, 46; see also Samuel S. Epstein, *Monsanto's Genetically Modified Milk Ruled Unsafe by the United Nations*, PR NEWSWIRE, Aug. 18, 1999, LEXIS, News Library, PRNEWS File (noting a finding by the public health committee commissioned by the European Commission that showed an increase in "highly potent variants" of IGF-1 and concluding that this increase posed major risks of breast and prostate cancer).

81. Hansen et al., *supra* note 79, at <http://www.consumer.org/food/bgh-codex.html>.

82. PURE FOOD CAMPAIGN, FOUND. OF ECON. TRENDS, RBGH WARNING AND WHAT YOU CAN DO TODAY, <http://www.holisticmed.com/bgh/bst-warn.txt> (last visited Jan. 7, 2001) (accrediting this knowledge to the FDA).

83. *Id.*

84. Susan Okie, *Experts Urge Steps to Stem Antibiotic Resistance*, WASH. POST, Aug. 26, 1997, at 7.

85. *Id.*

calling the developing resistance to these antibiotics “a major public health crisis.”⁸⁶ The CDC has determined there is a link between the injection of antibiotics into animals’ and humans’ growing resistance to antibiotics.⁸⁷

The FDA takes “precaution” by “spot checking” 500 samples of milk a year for twelve drugs in order to discard any milk with increased levels of these antibiotics.⁸⁸ While this should help stamp out consumers’ concern over antibiotic residue in their milk, there are reasons why this “spot checking” may be unsuccessful in alleviating these fears. Manufacturers use more than twelve types of drugs in treating cows and the checks do not detect all of these antibiotics.⁸⁹ Also disconcerting is the increase by the FDA in the allowable levels of antibiotics in milk from one part per billion to one part per million.⁹⁰ Therefore, the fact that the FDA requires “spot checking” for antibiotics does little to ease consumers’ fears considering the higher levels of antibiotics allowed and the possibility of drugs going undetected.

3. Mad Cow Disease

The FDA has looked into the increase in IGF-1 and the possibilities of antibiotic residues in milk treated with rBST. The use of this hormone, however, may cause another serious risk to human health that the FDA has yet to address—the potential for a cow treated with rBST to develop the debilitating disease bovine spongiform encephalopathy, commonly known as “mad cow” disease.⁹¹ Mad cow disease attacks the nervous system in cows and “eats microscopic sponge-like holes in a cow’s brain.”⁹² Critics are concerned that the increased protein needs in cows treated with rBST will, in turn, increase the use of “high protein feed”—a possible cause of the disease.⁹³ The protein supply in the feed typically comes from ground up animal meat—ultimately turning cows into carnivores.⁹⁴ One possible way by which cows contract mad cow disease is from eating “fodder containing processed flesh, especially nerve tissue, of sheep and other animals.”⁹⁵ Scientists believe there is a direct link between Creutzfeldt-Jakob disease, a disease with similar effects in humans, and eating meat from cows with mad cow disease.⁹⁶ There have not been any reliable studies done on the potential for rBST-treated cows to develop mad cow

86. Aboulafia, *supra* note 5, at 630 (quoting Tony Hiss, *How Now, Drugged Cow: Biotechnology Comes to Rural Vermont?*, HARPER’S MAG., Oct. 1994, at 80, 82).

87. *Id.* at 629-30.

88. Hansen et al., *supra* note 79, ¶ 2, at <http://www.consumer.org/food/bgh-codex.html>.

89. *Id.*

90. See Betty Martini, *Danger in Dairy*, ENVTL. TIMES, http://www.lisco.com/FranceTM/manipulation_genetique.html (last visited Oct. 29, 2000).

91. Emily Marden, *Recombinant Bovine Growth Hormone and the Courts: In Search of Justice*, 46 DRAKE L. REV. 617, 624 (1998).

92. *Questions and Answers on Mad Cow Disease*, TORONTO SUN, Mar. 30, 1996, at 16, LEXIS, News Library, TORSUN File [hereinafter *Questions and Answers*].

93. Marden, *supra* note 91, at 624.

94. David Ehrenfeld, Letter to Editor, *Blame Factory Farming for Mad-Cow Disease*, N.Y. TIMES, Jan. 16, 1996, at A16. Dr. Ehrenfeld is a professor of Biology at Rutgers University.

95. *Id.*

96. See *Questions and Answers*, *supra* note 92, at 16.

disease since the FDA has chosen not to address this particular concern.⁹⁷

C. Calling the FDA into Question

Judge Leval expressed disbelief in the majority's opinion that consumers' concerns about the findings of the FDA are unfounded and unreasonable.⁹⁸ He cited numerous possible reasons why people may have legitimate concerns despite the reassurances of the FDA.⁹⁹ Leval's dissent also noted that inadequate time and money given to testing, pressures from industry, unmanageable population samples, and inadequate advancement of new scientific techniques can all contribute to why a government agency may be unsuccessful in determining health effects.¹⁰⁰ Judge Leval pointed to a study conducted by the General Accounting Office ("GAO"),¹⁰¹ examining various drugs and their effects, which surfaced only after the approval by the FDA and use by the public.¹⁰² The GAO discovered 102 of the 198 drugs approved by the FDA between 1976 and 1985 had serious postapproval risks.¹⁰³ For some drugs, these risks included adverse reactions "leading to hospitalization, . . . severe or permanent disability, or [possibly even] death."¹⁰⁴ Judge Leval also cited his own experiences with cigarette smoking to illustrate how health hazards can surface even after a product is presumed safe.¹⁰⁵ All of these reasons substantially undermine the notion that the FDA's assurances relegate any consumer concern to mere "curiosity."

Since *Amestoy*, however, even more compelling reasons for consumer skepticism surrounding the FDA's findings have surfaced. On December 15, 1998, the Center for Food Safety ("CFS") and two dozen other consumer groups filed a petition to reverse the FDA's approval of rBST.¹⁰⁶ This petition came in response to "mounting evidence" against the FDA's findings, including studies from Canada contradicting the studies performed by the FDA.¹⁰⁷ The FDA conducted a study on rats before its approval of the hormone and concluded that "no toxicologically significant changes

97. See *Consumers Mop Up*, *supra* note 66, at 20.

98. *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 76 (2d Cir. 1996) (Leval, J., dissenting) (calling the majority's proposition "alarming and dangerous; at the very least, . . . extraordinarily unrealistic").

99. *Id.* at 77.

100. *Id.*

101. *Id.* (citing GAO Report, *FDA Drug Review: Postapproval Risks, 1976-85*, 1990 GEN. ACCT. OFF. REP. 1, 2-3). Congress requested this study after numerous attempts by Senator Patrick J. Leahy, Chairman of the Senate Agriculture Committee, to get the FDA to respond to his letters requesting information regarding the FDA's rBST testing methods. See *Abouafia supra* note 5, at 614.

102. *Amestoy*, 92 F.3d at 77 (Leval, J., dissenting).

103. *Id.* (citing GAO Report, *FDA Drug Review: Postapproval Risks, 1976-85*, 1990 GEN. ACCT. OFF. REP. 1, 2-3).

104. *Id.*

105. *Id.*

106. *Legal Challenge Filed with FDA to Remove Monsanto's BGH from the Market*, at <http://www.purefood.org/rBGH/remove.cfm> (Dec. 15, 1998) [hereinafter *Legal Challenge Filed with FDA*].

107. *Id.*

were noted . . . in rats [that were] administered [BGH] orally.”¹⁰⁸ Providing the findings of this study alone as its reason, the FDA did not mandate any human toxicological tests—a customary practice when approving a veterinary drug.¹⁰⁹

Health Canada filed a report directly contradicting the findings of the FDA studies. It found other studies that indicated the rats did absorb the hormone and that as many as twenty to thirty percent of the rats developed “distinct immunological reactions.”¹¹⁰ The Health Canada report also verified that cysts developed on the thyroids of treated rats and “infiltrated the prostate” in some rats.¹¹¹ Michael Hansen, a researcher with Consumer Policy Institute, argues that these studies should have “triggered a full human health review, including assessment of potential carcinogenic and immunological effects.”¹¹² There is some evidence indicating that the results in the original studies cited by the FDA were not thoroughly considered by the FDA because Monsanto conducted the studies, and the FDA based their assumptions of safety solely on the *summaries* of those studies.¹¹³ As a result of this evidence, the CFS and other consumer interest groups have alleged fraud on the part of the FDA and Monsanto.¹¹⁴

Allegations of FDA conflicts of interest also validate consumer concern and enhance a state’s interest in mandating labeling. Evidence of a significant overlap of officials and interested parties between Monsanto and the FDA has emerged since the court in *Amestoy* discounted any mistrust in the FDA. Monsanto’s chief researcher of rBST, Margaret Miller, was hired by the FDA as their deputy director of the Office of New Animal Drugs.¹¹⁵ Her role at the FDA was essentially to review her own research.¹¹⁶ While on board, Miller was behind the increase of allowable levels of antibiotic residue in milk.¹¹⁷ Michael Taylor, a powerful agent in the FDA that oversaw the approval process of rBST, was also Monsanto’s attorney.¹¹⁸

108. *Id.* (alteration in original).

109. *Id.*

110. *Id.*

111. *Id.*

112. *Id.*

113. *Id.*; see also Grogan & Long, *supra* note 80, at 43 (stating that the FDA requires only assurances from manufacturers that genetically engineered foods are safe).

114. *Legal Challenge Filed with FDA*, *supra* note 106, at <http://www.purefood.org/rBGH/remove.cfm>.

115. Aboulafia, *supra* note 5, at 623.

116. Martini, *supra* note 90, http://www.lisco.com/FranceTM/manipulation_genetique.html; see also Morris, *supra* note 56, at 306 (noting former Monsanto employee Margaret Miller’s clearance in a conflict of interest for her work with rBST at the FDA before she moved on to become a rapporteur at the Joint Expert Committees on Food Additives (“JECFA”).

117. See Martini, *supra* note 90, http://www.lisco.com/FranceTM/manipulation_genetique.html (alleging that the increase was 100 times).

118. See *id.*, http://www.lisco.com/FranceTM/manipulation_genetique.html; see also Aboulafia, *supra* note 5, at 624 (identifying Michael Taylor as the FDA’s deputy commissioner for policy). Conflicts of interest have been uncovered not only in the FDA, but also in international organizations reviewing rBST such as the JECFA, a subcommittee of the Food and Agriculture/World Health Organizations as well. In his report, Samuel S. Epstein claimed that the JECFA and other organizations are packed with “unelected, unaccountable . . . regulatory officials and industry consultants with no expertise in public health, preventive

Recently, a citizens group entitled Council of Canadians ("CoC") raised "serious questions about the objectivity of the expert panels."¹¹⁹ CoC asserted that Rejeanne Gougeon, a human-safety panelist, consulted for Monsanto on the hormone.¹²⁰ The risk of undue influence from the overlap of officials prompted U.S. Senator Eugene Whelan to testify that he would not place weight on any of the testimony from these organizations on the safety of the hormone in hearings conducted by the Senate.¹²¹

D. Consumer Concern Sufficient for Article III Standing

Around the same time parties were preparing arguments regarding Vermont's mandatory labeling law in *Amestoy*, the U.S. District Court for the Western District of Wisconsin was hearing *Barnes v. Shalala*,¹²² an action brought to suspend the FDA's approval of rBST until more tests could be conducted. In a hearing regarding the defendants' motion to dismiss for lack of subject matter jurisdiction, Judge Crabb had to determine whether the plaintiffs had Article III standing under either the Food, Drug and Cosmetics Act or the National Environmental Policy Act.¹²³ Three elements must be satisfied in order to have standing under Article III of the Constitution: (1) an injury or threat of injury, (2) causation traceable to the defendant's conduct, and (3) likelihood that a decision in the plaintiff's favor would provide redress.¹²⁴ To satisfy the first element, the injury or threat of injury must be "real and immediate"¹²⁵ and "concrete and particularized" going beyond "intellectual or academic curiosity."¹²⁶

Two of the plaintiffs were consumers of milk and milk products and alleged that their harm was the inability to consume dairy products due to the lack of labeling and impossibility of choosing products from untreated cows.¹²⁷ These plaintiffs also expressed a sincere fear that consuming products from cows treated with rBST would be harmful to their health.¹²⁸

The defendants in *Shalala* attempted to dismiss consumer fear as speculative and unrealistic and argued that such fear was nothing that the voluntary labeling of milk allowed by the FDA could not remedy.¹²⁹ Judge Crabb, however, sided with the

medicine, and carcinogenesis." Epstein, *supra* note 80. Epstein's report cited overlap of regulatory and industry officials within these committees and discussed the resulting problems in objectivity in the rBST reviews. *Id.*

119. Morris, *supra* note 56, at 306 (internal quotes omitted).

120. *Id.*

121. *Id.*

122. 865 F. Supp. 550, 556 (W.D. Wis. 1994).

123. *Id.* at 554, 558.

124. *Id.* (citing *Family & Children's Ctr., Inc. v. Sch. City of Mishawaka*, 13 F.3d 1052, 1058 (7th Cir. 1994) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992))).

125. *Id.* at 558 (quoting *Schmidling v. City of Chicago*, 1 F.3d 494, 498 (7th Cir. 1993)).

126. *Id.* (quoting *Family & Children's Ctr., Inc. v. Sch. City of Mishawaka*, 13 F.3d 1052, 1058 (7th Cir. 1994)).

127. *Id.*

128. *Id.*

129. *Id.*

consumer-plaintiffs¹³⁰ and found their alleged injuries sufficient.¹³¹ Judge Crabb noted that voluntary labeling, while able to mitigate some of the harm of not knowing whether the product contained milk from treated cows, is in no way complete redress.¹³² Even though the court here denied a chance for all concerns and fears to be heard in a court of law, this case makes it easier for plaintiffs wishing to bring claims based on consumer fear to gain standing.

E. Why Mandatory Labeling?

Even if a state were successful in proving the legitimate and substantial nature of its interest in consumer concern, there is still a question left in the four-part *Central Hudson* analysis that the court in *Amestoy* did not consider. This involves whether labeling is necessary in order to directly advance the state's interest. There is evidence that mandatory labeling is the best option to remedy the concerns of the public with regard to their ability to make conscious choices about the foods they buy.

In the spring of 1999, Congress received 500,000 signatures calling for mandatory labeling of all genetically altered foods.¹³³ Similarly, the FDA faces two recent lawsuits demanding labeling.¹³⁴ Some people do not believe that mandatory labeling is necessary given the voluntary labeling allowed by the FDA's interim guidance. Recently, however, consumers, retailers, and officials have felt the effects of the lack of labeling requirements on the ability of consumers to decide for themselves. Richard Wolfson, the chairman of Canada's Consumer Right to Know Campaign, recognized that mandatory labeling was the only way to sufficiently trace and measure any health effects and the only way to ensure that consumers were protected and had the right to choose.¹³⁵ Following similar logic, Japan has required labeling of genetically altered foods.¹³⁶

People with religious or moral reasons for not wanting to consume products from treated cows will find it virtually impossible to identify and eliminate such products

130. Not all of the plaintiffs in the case were successful in establishing Article III standing. The court dismissed the actions of the plaintiffs known as the "sellers of dairy products" (various wholesalers, store owners, and restaurant owners), stating that their allegations were based on too much speculation. *Id.* Likewise, the plaintiffs that were health care professionals, veterinarians, and counselors found their case dismissed for unsubstantiated injuries. *Id.* at 561. The Foundation of Economic Trends, a not-for-profit organization, claimed a drain of resources as its injury, but the court dismissed this claim as well. *Id.* The only other plaintiffs to emerge successful in not getting their claim dismissed were the dairy farmers. *Id.* at 560.

131. *Id.*

132. *Id.* (stating that the complete cure for plaintiffs' want is a change in the FDA's approval). However, the insufficiency of voluntary labeling in helping consumers make informed decisions noted by Judge Crabb, and her opinion that the fear of consuming products from hormone treated cows is sufficient for standing, parallel the arguments made by the district court in *Amestoy* and Judge Leval.

133. See Grogan & Long, *supra* note 80, at 43.

134. *Id.*

135. *Id.*

136. *Id.*

given the existence of dairy in so many food items.¹³⁷ Two major natural-foods supermarket chains are facing some difficulties after they announced the plan to "rid their shelves of products that contain biotech ingredients."¹³⁸ Manufacturers are not required to label whether their ingredients contain any genetically modified products, including the use of rBST, making the goal of these supermarkets difficult to accomplish for years.¹³⁹ Margaret Whittenberg, vice-president of Whole Foods, a chain of 103 stores in twenty-two states, recognized an "absolute anger" among her customers that they did not know all the ingredients of the foods they wished to purchase.¹⁴⁰ Wild Oats, another major health-food supermarket attempting to rid itself of genetically modified foods, is facing similar difficulties produced by a lack of labeling.¹⁴¹ Until these chains are successful, citizens will likely continue to consume genetically engineered foods against their will despite their best efforts not to do so.

The actions of Monsanto exemplify the usefulness of mandatory labeling laws in combating pressures applied by large, powerful corporations. In the 1980s alone, Monsanto invested an estimated one-half billion dollars towards developing the hormone.¹⁴² With such an enormous investment early on, Monsanto had a lot to lose—especially if consumers opted to buy products not made with milk taken from a treated cow. Brian Tokar, a professor of ecology at a small Vermont college, accused Monsanto of issuing threats to sue some small dairy manufacturers if they voluntarily engaged in any advertising that their milk was free of the rBST hormone.¹⁴³ Monsanto actually levied suit against two dairy manufacturers for labeling their products rBST-free and wrote letters to 2000 other manufacturers threatening to sue them if they did the same.¹⁴⁴ Monsanto, backed by the FDA, stated that to label "rBST-free" is misleading because there was no reported incidence of rBST existing in the milk itself.¹⁴⁵ Needless to say, threats issued by a large, powerful company, regardless if they attack specific language, may be enough to stifle labeling by smaller participants in the dairy industry. Allowing states to mandate particular labeling, including the FDA's qualified statement that rBST is safe, would eliminate such problems and strip Monsanto of its ability to use intimidation to discourage voluntary labeling.

III. STATE REACTIONS

Despite the holding in *Amestoy*, some states' legislators are proposing mandatory labeling laws in their states in response to concern among their citizens. For example, New York Assemblyman McEneny, along with five other members of the Assembly,

137. *Id.* at 46-47.

138. Louise Branson, *Backlash Grows in US Against GM Foods*, STRAITS TIMES (Sing.), Jan. 6, 2000, 2000 WL 2962540.

139. *Id.*

140. *Id.*

141. *Id.*

142. Aboulafia, *supra* note 5, at 606.

143. Brian Tokar, *Monsanto: A Checkered History*, 28 *ECOLOGIST* 254, 258 (1998).

144. Aboulafia, *supra* note 5, at 618.

145. *Id.* at 617.

introduced a bill requiring mandatory labeling on February 1, 2001.¹⁴⁶ There are forty-four cosponsors listed on the bill.¹⁴⁷ The bill states the reasoning as follows:

The Legislature hereby finds and declares that there has been a substantial public debate concerning the possible health and safety effects of milk and milk products produced from cows injected with Recombinant Bovine Somatotropin There is also substantial evidence that when food or food products . . . are enhanced by the influence of foreign substances . . . there can be a health and safety impact upon [the consumers]. The Legislature also finds and declares that although at present the exact impact, if any, of the direct link between [rBST] and disease or affliction is undetermined, at their inception the enhancement of food or food product, such as milk or other naturally produced human consumables, by the influence of foreign other substances . . . were equally undetermined, only to be found later to cause a significant health and safety impact as well as a direct link to human disease or affliction.¹⁴⁸

The bill proposes that mandatory labeling will best serve the interests of the citizens of New York by allowing them to determine which milk and milk products were produced from cows treated with rBST.¹⁴⁹ Section 266-2 of the bill expresses that labeling all dairy products is the "most prudent and appropriate way to inform its citizens"¹⁵⁰—disputing the argument that voluntary labeling is enough to allow consumers to make educated purchases.

Similarly, on February 10, 2000, Rhode Island representatives responded to the controversy surrounding rBST by proposing a bill that would require labeling of dairy products as well.¹⁵¹ This bill calls for *clear and conspicuous* labeling on the container of any product containing milk derived from cows treated with rBST and imposes monetary fines for violations.¹⁵² If passed, the bill will become an act to take effect as early as June 30, 2001.¹⁵³ Although these states are undoubtedly going to have to litigate these proposals if and when they become law, the mere fact that the Second Circuit opinion in *Amestoy* does not curtail their efforts is an encouraging sign that the issue of mandatory labeling is still prevalent today.

CONCLUSION

More state legislators are listening to the valid concerns of their constituents and are attempting to forge through the door left open by the appellate court in *Amestoy*. New York and Rhode Island are attempting the very legislation that an appellate court struck down in Vermont. New York legislators state the exact same reasons for

146. See Assemb. 3586, 2001 Leg., 224th Ann. Sess. (N.Y. 2001), WL 2001 NY A.B. 3586 (proposing to amend the general business law by adding Article 16-A, which includes mandatory labeling laws).

147. *Id.*

148. *Id.* § 266-1.

149. *Id.* § 266-2.

150. *Id.*

151. H.R.7511, 1999 Leg., 1999-2000 Legis. Sess., § 2-31.1 (R.I. 2000), WL 1999 RI H.B. 7511.

152. *Id.*

153. *Id.*

issuing mandatory labeling laws but, if taken to court, will likely have more compelling evidence to support their case and, therefore, a better chance of meeting the standard set out by the court in *Amestoy*. Since that case, much more evidence and information regarding the effects of rBST on cow and human health and questionable activity on the part of the FDA have emerged. If the states are successful in passing the first part of the test set out in *Central Hudson*, they still face the question of whether mandatory labeling is essential to the advancement of their interests.

. The decision of any court to uphold mandatory labeling laws passed by states will have a great impact on far more than just the dairy products sitting on grocery shelves. There is considerable evidence indicating that mandatory labeling is necessary to maximize the choice consumers have over the products they purchase. Mandatory labeling may also be a state's solution to the problems surrounding the influence Monsanto has exerted over the dairy industry and federal agencies. As long as a state is careful in its choice of words on the label—asserting truthful, non-misleading information—there is quite possibly enough evidence for it to emerge victorious in convincing the court that mandatory labeling appeases a legitimate consumer concern, places the choice in the proper hands, and is not too restrictive in accomplishing its goals.

